



U.S. Department
of Transportation
**Research and
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400 Seventh St., S.W.
Washington, D.C. 20590

Ms. Peggy Kollars
Laboratory Education Specialist
Sharp Pathology Laboratory
5325 Metro Street
San Diego, CA 92110

Reference No.: 02-0074

Dear Ms. Kollars:

This responds to your letter requesting clarification on the definition and exceptions for diagnostic specimen under the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180). Specifically, you ask whether a blood sample being shipped within the State of California for the purpose of quantification of HIV is considered a diagnostic specimen or an infectious substance.

A blood sample being shipped for diagnosis is considered a diagnostic specimen. The HMR define a diagnostic specimen as "any human or animal material, including, but not limited to, excreta, secretions, blood, blood components, tissue, and tissue fluids, being shipped for purposes of diagnosis" (see § 173.134(a)(2)). A diagnostic specimen, even one known to contain an infectious substance, is excepted from the HMR unless the material meets the definition of another hazard class. However, a diagnostic specimen that is infectious may be subject to the regulations of other federal agencies with responsibilities for these materials.

I hope this information is helpful.

Sincerely,

Hattie L. Mitchell
Chief, Regulatory Review and Reinvention
Office of Hazardous Materials Standards



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Corbin
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Infectious Substance
02-0074

DEPARTMENT OF PATHOLOGY March 5, 2002

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Edward T. Mazzullo, Director
Office of Hazardous Materials Standards
U.S. Dept. of Transportation
400 Seventh Street, S.W.
Washington, DC 20590

Dear Mr. Mazzullo:

I have a question regarding intrastate transport of diagnostic specimens for testing versus testing for infectious substances (e.g. testing for confirmation or quantitation of an infectious substance) under the Hazardous Materials Regulations (HMR; 40 CFR, Parts 171-180).

Is a blood sample known to contain HIV and being shipped by road within the state of California for purpose of quantification of HIV considered to be a diagnostic specimen with no specific handling requirements or is it considered an infectious substance with specific infectious substance handling requirements?

I would appreciate a prompt reply.

Sincerely,

Peggy Kollars

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